Pall Corporation

PRODUCT SAFETY DATA INFORMATION

Date: 06 Jan 2023

Data Sheet Number: PSDI Acrocap with Versapor RC_Family
Revision: 2

SECTION 1 – Product Identification

This 'Product Safety Data Information' Sheet covers Pall Medical Acrocap Filter with Versapor® RC product variants

Product name(s): Hydrophobic air filter

Part Number(s): See appendix 1 – Air elimination filters for patient protection only and for removal of inadvertent particulate debris and microbial contaminants.

For further information on Pall products, please visit Pall at https://www.pall.com/en/about-pall.html

SECTION 2 - Hazards Identification

Product definition: Article.

These products are not classified as hazardous according to REACH Regulation 1907/2006, or European CLP/GHS Regulation 1272/2008.

Suitable gloves must be worn when handling these membranes out of their packaging, to address any concerns related to residual levels of PFOA (less than 25 ppb) and PFOA-related compounds (less than 1000ppb) related to the material as supplied.

GHS Signal word: No signal word.

Hazard statements: No known significant effects or critical hazards.

Special packaging requirements: None.

SECTION 3 - Materials of Construction

3.1 The filters detailed in Section 1 are comprised of the following materials:

Filter assembly

Material Name	Product(s)	CAS Number
Modified acrylic copolymer housings	All listed	Supplier proprietary information
Acrylic copolymer membrane	All listed	Pall proprietary information

Repel surface treatment	All listed	Pall proprietary information

These products are not known to contain BADGE, NOGE, or BFDGE.

Trace additives will be present in the plastic components.

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the article.

Please note that in May 2019 the Stockholm Convention moved to add perfluorooctanoic acid (PFOA) and/or PFOA-related compounds to its POPs Annex A with the intention of restricting the use of PFOA and its related compounds to a limited range of applications within the ratifying countries.

These products are not known to contain perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds at levels in excess of:

PFOA and its salts	25 ppb
PFOA related compounds	1000 ppb

The above statement is based on a risk assessment approach considering the supplier's information on the key constituent in the surface treatment concerning to PFOA, and Pall testing of the finished membrane for residual PFOA. Pall testing of the key constituent in the surface treatment for PFOA related compounds was conducted.

Please note that the membrane is known to contain residual PFAS substances and as such may require registration by the user in the US State of Maine from January 1st 2023 in line with the requirements of State of Maine bill LD 1503.

Concerning the requirements of European Commission Regulation (EU) 2021/1297 amending Annex XVII to Regulation (EC) No 1907/2006 in regards to perfluoro carboxylic acids (PFCAs) containing 9 to 14 carbon atoms in the chain, their salts and related substances, C_9 to C_{14} PFCAs, their salts and C_9 to C_{14} PFCA-related substances are not employed in the production of these products in the Pall manufacturing facility

There are no current SVHC substances known to be present in the finished articles above 0.1%.

There are no current ROHS2 Directive (2011/65/EU) and amendment (2015/863) substances of concern (including Lead, Cadmium, Mercury, Hexavalent Chromium, Polybrominated biphenyl (PBB), Polybrominated diphenyl ether (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl phthalate (DBP) and Di-isobutyl phthalate (DIBP)) known to be present in the materials employed in excess of the limits laid down, based on information from our suppliers and knowledge of substances used within Pall the manufacturing facility.

Pall Medical filters do not employ natural rubber latex, or latex derivatives in their construction.

Pall Medical membranes and filters do not knowingly contain materials of direct animal origin i.e. animal parts, tissues, or body fluids or derivatives. They are not known to be present in the raw materials nor are they intentionally added in the manufacturing process, but Pall does not test for them

SECTION 4 - First Aid Measures

4.1 First aid measures

Always address any contaminants present on the filter as the result of use.

Eye Contact:	Eye injury could result from physical impact. Get medical attention immediately.
Inhalation:	Inhalation is not considered a likely route of exposure for the filter product as supplied by Pall.
Skin Contact:	Wash with soap and water. If irritation persists, get medical attention.
Ingestion:	This material is not intended for ingestion and is not expected to present an ingestion hazard in the form and quantities present in a work-place setting. However, if ingestion occurs, seek medical attention.
Protection of first-aiders:	No action shall be taken involving any personal risk or without suitable training.

4.2 Key symptoms and effects

No known significant effects or critical hazards related to the materials of construction of the filter as supplied.

SECTION 5 - Fire Fighting Measures

5.1 Extinguishing media

Select an extinguish medium suitable for surrounding / working environment.

For filter set alone use dry chemical, CO2, water spray (fog) or foam.

5.2 Specific Hazards

Consult the SDS details of product being filtered for specific advice.

For the filter alone: No specific fire or explosion hazard.

Hazardous thermal decomposition products: CO, CO_2, Acrid Smoke

5.3 Advice to Fire Fighters

Special precaution required. Fire-fighters should wear appropriate protective equipment, including self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6 - Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

No special measures are required in respect of the filters in the unused condition as supplied.

For used filters always address any contaminants present on the filter as the result of use.

6.2 Environmental precautions

For unused filter modules, place in designated waste container appropriate to the materials of construction listed in Section 3 and dispose of in accordance with local regulations via a licenced waste disposal contractor.

For used filter modules, using clear-up, containment and appropriate PPE measures related to the product being filtered and the materials of construction detailed in Section 3.

6.3 Spillage containment and cleaning up

Use suitable equipment to collect the filter material and place in a designated, labelled waste container.

Care should be taken to consider the nature of any contamination on the filter as the result of use and suitable PPE employed for handling medical waste.

Dispose of waste via a licensed waste disposal contractor.

SECTION 7 – Handling and Storage

7.1 Handling

Put on appropriate personal protective equipment for the working environment (See Section 8). Consult details of product being filtered for specific advice. Avoid activities that can damage the filter.

Follow good hygiene practices. Eating, drinking and smoking are generally prohibited in areas where this product is handled, stored or processed – exceptions are made on the guidance of local medical advice. Staff must follow standard work-place hygiene before eating, drinking or smoking after using this product. Wear gloves to prevent contamination of the filter cartridge and maintain cleanliness of the unused filter.

7.2 Storage

In the received condition, special protective equipment is not needed during handling and normal use of these filters. However, gloves are recommended to prevent contamination of the filter and maintain cleanliness. Handling of used filters must take into account the nature of potential contaminants.

The article is supplied dry, without the presence of any preserving fluid.
Store in clean, dry conditions suitable for a medical device.

Handle with care to avoid damage.

Do not expose to direct sunlight during storage, or other radiation or direct weather conditions.
Store in original shipping bag or boxing.
Ensure careful handling to avoid physical damage. Ensure shipping bag and seals are intact prior to use - do not use if damaged.

Please also consult Pall for further instructions for use information on the product prior to use.

SECTION 8 - Exposure Controls/Personal Protection

8.1 Control parameters

Occupational Exposure limits: None required.

Recommended monitoring procedures: None required

8.2 Exposure controls

There are no special ventilation requirements for the article as supplied in the new and unused condition.

Hygiene Measures: No special measures required. Good hygiene practice in line with local working environmental requirements and medical guidelines.

Hand protection: Disposable gloves are recommended to ensure filter remains clean during installation.

Environmental Exposure Controls: Not normally required for the filter itself as supplied.

After the filter has been used additional exposure controls care should be taken in line with the nature of any contaminant on the filter as a result of its use.

SECTION 9 - Physical and Chemical Properties

Appearance: Disposable filter/filter set

Physical state: Solid

Colour: Various

Solubility:	All components insoluble in water. Acrylic components readily soluble in esters, ketones and chlorinated hydrocarbons
Auto-ignition temperature:	Acrylic: 440 °C (830 °F), decomposition begins at 250 °C (482°F)
Sensitivity to shock:	Mechanical / thermal shock can result in damage to the filter

SECTION 10 – Stability and Reactivity

Reactivity:	The filter is stable under the recommended conditions of use and storage.
Chemical Stability:	The filter is stable under recommended conditions of use and storage.
Hazardous Polymerisation:	Polymerisation will not occur under recommended conditions of use and storage.
Other hazardous reactions:	Consult details of product being filtered for specific advice. Under normal conditions of storage and use, no hazardous reactions will occur.
Conditions to Avoid:	Avoid hot surfaces or other conditions that soften, swell or adversely affect the filter or its materials of construction. Do not allow fluids to freeze on the filter
Incompatible Materials:	Strong Acids, alkalis and oxidising Agents (e.g. Perchloric Acid, nitric acid), alkali metals, strong alkalis and reducing agents, organic acids
Decomposition Products:	Under recommended conditions of use or storage, no hazardous decomposition products will be produced.

SECTION 11 - Toxicological Information

The information in this section contains generic advice and guidance in respect of the unused filter as supplied. Consult SDS details of the product being filtered for specific advice and recommendations.

11.1 Acute Toxicity

Based on typical information for the material type named, this information has not been determined specifically for Pall Medical filters

Mutagenicity / Carcinogenicity / Reproductive Toxicity / Teratogenicity: No known concern for the materials of construction of the filter as supplied (new and unused)

Aspiration Hazard: Not applicable for un-used filter.

Potential acute health effects: No known significant effects or critical hazards for the unused filter as supplied.

11.2 Chronic health effects

No known significant effects or critical hazards for the unused filter as supplied.

Carcinogenicity: No specific test data available, no evidence for hazardous properties

---

SECTION 12 - Ecological Information

Pall Medical filters are not expected to degrade in contact with soil or water under ambient conditions.

SECTION 13 - Disposal Information

The information in this section contains generic advice and guidance.

Product

Methods of disposal:

Unused as supplied filters: Disposal/handling of the un-used filters should be in-line with national legislation and local regulatory requirements for the materials present. Unused filters may be used as land-fill.

Hazardous Waste**:** To the best of our knowledge, this product if unused is not regarded as hazardous waste as defined by the EU Directive 91/689/EEC and amendments.

Used filters should be disposed of as clinical waste due to the nature of the contaminants on the filters as a result of use. Therefore, used filters may be classified as hazardous – clinical waste.

Packaging

Bagging: Polyethylene

Box: Cardboard

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled where suitable arrangements and facilities exist. Incineration or landfill should only be considered where re-cycling is not feasible.

SECTION 14 - Transport Information

The clean and un-used filter, supplied in its original packaging, is not classified as dangerous goods under ADR, RID, IMDG or IATA regulations.

SECTION 15 – Change History

Rev number	Description of change
1	Initial release
2	Revision performed to replace incorrectly formatted Rev 1 on webpage, to add state of Maine statement and to update animal derived substances statement

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above Pall Corporation, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any materials is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

APPENDIX 1

Part Number	Description
6144423	Hydrophobic air filter

Pall Corporation

PRODUCT SAFETY DATA INFORMATION

Date: 06 Jan 2023

Data Sheet Number: PSDI Acrocap with Versapor RC_Family
Revision: 2